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Contractor	YOUNGER LABS INC		
Document Title	INITIAL SUBMISSION: TOXICOLOGICAL INVESTIGATION OF: DEQUEST 2010 WITH COVER LETTER DATED 081392		
Chemical Category	DEQUEST 2010		

8(e)

CAP

9747

(COMPLIANCE AUDIT PROGRAM)

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Monsanto

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Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

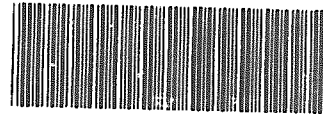
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ENVIRONMENT, SAFETY & HEALTH

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Office of Toxic Substances
Environmental Protection Agency
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Washington, DC 20460

Attention: Section 8(e) Coordinator (CAP Agreement)

This submission is pursuant to the TSCA Section 8(e) Compliance Audit Program and
CAP Agreement #8ECAP-0036.

The information included herein is characterized as follows:

Chemical Identity - DEQUEST 2010

Chemical CAS No. - 002809214

Information/Study Type - II,B,2,b/Acute Toxicity/Irritation Study

Information/Study Identification - Toxicological Investigation of: DEQUEST 2010
YO-65-074

Identification of Reportable Endpoint: EYE CORROSIVE

Previous TSCA 8(e) or PMN submissions, if any, for the reference chemical can be found in
Appendix A.

It should be noted that this summary is not all inclusive. Therefore, it may not highlight all
adverse effects that EPA may judge to meet TSCA 8(e) reportability. This submission/report does
not contain confidential business information.

Sincerely,

J. R. Condray
Director, Regulatory Management
(314) 694-8883

YOUNGER LABORATORIES

Biochemists ... Pharmacologists ... Analysts

128 CLIFF CAVE ROAD

SAINT LOUIS, MO., 63129

PHONE: TILDEN 6-2540

Certificate of Analysis

September 7th, 1965

SUBJECT -

Toxicological Investigation Of DEQUEST ^(R)2010

Monsanto Sample Number 100

Monsanto Project Number Y-65-74

STUDY CONDUCTED FOR -

Monsanto Company, St. Louis, Missouri

EXPERIMENTAL PROCEDURE -

A) Oral LD₅₀ (Rats, Mixed Sex)

The diluted compound was fed by stomach tube to Sprague-Dawley strain albino male and female rats.

After the approximate Minimum Lethal Dose was determined, groups of male and female rats were fed in increasing doses at increments of 0.1 fractional log intervals at four levels designed to blanket the toxicity range thereby supplying data for calculation of the LD₅₀ which was done according to a modification of the method of E. J. de Beer.

Observations were made for toxic symptoms and the viscera of the animals that succumbed were examined macroscopically.

The data, together with the dilution at which the compound was fed, are shown in Table I.

B) Skin Absorption MLD (Rabbits, Mixed Sex)

The undiluted compound was applied in increasing doses at increments of 0.2 fractional log intervals to the closely clipped, intact skin of New Zealand white male and female rabbits.

The treated areas were covered with plastic strips and the animals placed in wooden stocks for periods up to twenty-four hours, after which time they were assigned to individual cages.

Observations were made for toxic symptoms and since there were no deaths, no autopsies were performed.

The data are shown in Table II.

EXPERIMENTAL PROCEDURE - (Continued)

C) Skin Irritation (Rabbits)

The undiluted compound was applied to the clipped, intact skin of albino rabbits and removed after twenty-four hours. The application was covered with plastic strips to retard evaporation and avoid contamination.

Observations were made over a period of several days for irritation.

The data, scored according to the method of Draize, Woodard and Calvery (Journal of Pharm. and Exp. Therapeutics, Volume 82, December, 1944) are shown in Table III.

D) Eye Irritation (Rabbits)

0.1 Milliliter of undiluted sample was placed in the conjunctival sac of the right eye of each of three albino rabbits and observations made over a period of several days for inflammation.

The eye of animal #1 was rinsed with warm isotonic saline solution after twenty-four hours exposure, the eye of animal #2 after twenty-four hours exposure, and the eye of animal #3 after four seconds exposure.

The data, scored according to the method of Draize, et al, are shown in Table IV.

SUMMARY -

DEQUEST [®] 2010

A) Oral LD₅₀ (Rats, Mixed Sex)

The Oral LD₅₀ for male and female rats was placed at 3130 milligrams per kilogram with lower and upper limits of 2660 to 3665 milligrams per kilogram. The compound was classed as slightly toxic by oral ingestion in male and female rats.

B) Skin Absorption MLD (Rabbits, Mixed Sex)

The highest application of 10,000 milligrams per kilogram was found to be non-lethal by skin absorption in male and female rabbits. The compound was classed as practically non-toxic by skin absorption in male and female rabbits.

C) Skin Irritation (Rabbits)

The compound was classed as a moderate skin irritant when applied undiluted to intact rabbit skin. The average maximum score was 3.6 out of a possible 8 in twenty-four hours.

D) Eye Irritation (Rabbits)

The compound was classed as a corrosive eye irritant. The maximum score was 90.0 out of a possible 110 in seventy-two hours.

YOUNGER LABORATORIES

Fred M. Younger
BY: FRED M. YOUNGER

To: Monsanto Company
 St. Louis, Missouri
 Younger Laboratories Certificate of Analysis - Page 3 (9/7/65) - Y-65_74

TABLE I

THE ORAL LD₅₀ OF 'DEQUEST 2010' FOR RATS

Sample Fed As A 50.0% Aqueous Solution

<u>Animal No. - Sex</u>	<u>Weight Gm.</u>	<u>Dose Mg./Kg.</u>	<u>Fate</u>
1- Female	225	2000	Survived
2- Female	220	2000	Survived
3- Male	245	2000	Survived
4- Male	260	2000	Survived
5- Female	230	2000	Survived
6- Female	240	2510	Survived
7- Male	255	2510	Survived
8- Male	270	2510	Survived
9- Female	225	2510	Died
10- Female	235	2510	Survived
11- Male	250	3160	Died
12- Male	265	3160	Survived
13- Female	230	3160	Survived
14- Female	235	3160	Died
15- Male	260	3160	Died
16- Male	250	3980	Died
17- Female	245	3980	Died
18- Female	230	3980	Died
19- Male	260	3980	Survived
20- Male	255	3980	Died

DISCUSSION -

The Oral LD₅₀ for male and female rats was placed at 3130 milligrams per kilogram with lower and upper limits of 2660 to 3665 milligrams per kilogram.

The compound was classed as slightly toxic by oral ingestion in male and female rats.

Survival time was one to eight hours with most deaths occurring in one to two hours.

Toxic symptoms included weakness in minutes followed by dyspnea and collapse.

At autopsy there was inflammation of the gastric mucosa and hemorrhagic areas in the lungs.

T A B L E II
THE MINIMUM LETHAL DOSE OF 'DEQUEST 2010'
BY SKIN ABSORPTION IN RABBITS

Sample Applied Undiluted *

Animal No. - Sex	Weight Kg.	Dose Mg./Kg.	Weight Change	Fate
			5 Days Later Kg.	
1 - Female	2.6	1,000	+ 0.2	Survived
2 - Male	2.9	1,580	+ 0.1	Survived
3 - Female	2.7	2,510	0.0	Survived
4 - Male	3.0	3,980	- 0.2	Survived
5 - Female	2.6	6,310	- 0.3	Survived
6 - Male	2.9	10,000	- 0.2	Survived

* The sample was applied over a period of two hours to the skin of animals #5 and #6. The compound dried fairly rapidly in all instances even though covered with plastic. Accordingly, the surface was kept moist with a fine spray of water applied every two hours during the eight hour work day.

DISCUSSION -

The highest application of 10,000 milligrams per kilogram was found to be non-lethal by skin absorption in male and female rabbits.

The compound was classed as practically non-toxic by skin absorption in male and female rabbits.

Toxic symptoms included moderate weakness and much discomfort at the higher dosage levels but no paralysis developed.

The material in this report is to be used in development of the product and may be given to responsible sales contacts, but it is not to be used by them in advertising copy. The source of this material is not to be disclosed until it appears in formal publications. No exceptions to the established rule may be made without the approval of the Medical Department in St. Louis. Customer inquiries regarding matters of toxicity are to be referred as before to the Medical Department in St. Louis for reply.

— Monsanto Chemical Company

T A B L E I I I

SKIN IRRITATION IN RABBITS AFTER APPLICATION OF 'DEQUEST 2010'

Sample Applied Undiluted

<u>Animal Number</u>	Numerical Evaluation At The End Of					
	<u>1 Hour</u>	<u>24 Hours</u>	<u>48 Hours</u>	<u>72 Hours</u>	<u>120 Hours</u>	<u>168 Hours</u>
1	2	3	3	2	1	0
2	3	4	3	3	2	1
3	2	4	3	3	2	1
Average	2.3	3.6	3.0	2.6	1.6	0.6

DISCUSSION -

The compound was classed as a moderate skin irritant when applied undiluted to intact rabbit skin.

The average maximum score was 3.6 out of a possible 8 in twenty-four hours.

Well-defined redness with one instance of very slight edema was noted after one hour. Overnight there was moderate erythema and slight edema for an average score of 3.6. Following removal of the application, inflammation gradually reduced to two instances of very slight redness in seven days.

Tissue necrosis occurred when the compound was in contact with abraded areas for twenty-four hours.

To: Monsanto Company
St. Louis, Missouri

Younger Laboratories Certificate of Analysis - Page 6 (9/7/65) - Y-65-74

T A B L E IV

EYE IRRITATION IN RABBITS AFTER APPLICATION OF 'DEQUEST 2010'

Sample (0.1 Milliliter) Applied Undiluted

<u>Animal Number</u>	<u>Numerical Evaluation At The End Of</u>					
	<u>1 Hour</u>	<u>24 Hours</u>	<u>48 Hours</u>	<u>72 Hours</u>	<u>120 Hours</u>	<u>168 Hours</u>
24-HOUR EXPOSURE						
1	42	57	75	90	90	90
2	49	69	83	90	90	90
Average (1-2)	45.5	63.0	79.0	90.0	90.0	90.0
4-SECOND EXPOSURE						
3	31	36	29	22	13	4

DISCUSSION -

The compound was classed as a corrosive eye irritant.

The maximum score was 90 out of a possible 110 in seventy-two hours.

Much discomfort was shown immediately following application.

24-HOUR EXPOSURE

Copious discharge, translucent cornea with iris details moderately obscured, particularly the lower half, moderately severe erythema, and swelling with partial eversion of the lids developed within one hour. In twenty-four and forty-eight hours corneal opacity increased and the conjunctivae became beefy red. The lower half of the cornea became opaque in seventy-two hours and remained so throughout the seven day observation period. With the lower portion of the iris invisible and not responding to light, it was evident that ~~sight~~ had been destroyed. The upper half of the eye was only moderately affected due to the fact that the dose was concentrated in the conjunctival sac.

4-SECOND EXPOSURE

After one hour there was moderate lacrimation, mild edema and erythema, and mild corneal cloudiness with iris details clearly visible. Congestion increased slightly in twenty-four hours but decreased thereafter with the result that only very slight redness remained after seven days.